IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PHILADELPHIA FEDERATION OF TEACHERS

HEALTH AND WELFARE FUND,

INDIVIDUALLY AND ON BEHALF OF ALL

OTHERS SIMILARLY SITUATED,

1816 CHESTNUT STREET

PHILADELPHIA, PA 19103

CASE NO.

PLAINTIFF,

v.

PURDUE PHARMA, L.P. 201 TRESSER BOULEVARD STAMFORD, CT 06901

AND

Purdue Pharma, Inc. 201 Tresser Boulevard Stamford, CT 06901

AND

Purdue Frederick Company, Inc. 201 Tresser Boulevard Stamford, CT 06901 And

ABBOTT LABORATORIES, INC. 100 ABBOTT PARK ROAD ABBOTT PARK, IL 60064

DEFENDANTS.

CLASS ACTION COMPLAINT

Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund (hereinafter, the "PFTHW" or "Plaintiff"), individually and on behalf of all others similarly situated, by and through its attorneys ANAPOL WEISS and EDELSON PC, hereby brings this Class Action seeking relief from Defendants Purdue Pharma L.P., Purdue Pharma Inc., the Purdue

Frederick Company, Inc. (collectively, "PURDUE") and Abbott Laboratories, Inc. ("ABBOTT") (collectively "Defendants") and aver as follows:

INTRODUCTION

1. Despite well-recognized legal principles requiring Defendants to be truthful and forthright in its representations and marketing activities regarding its pharmaceuticals, Defendants have engaged in an intentional, decades-long pattern of deceptive and misrepresentative conduct that has impermissibly minimized the grave medical risks associated with utilizing opioids to treat long-term and/or chronic medical conditions. In addition to contributing to an epidemic of catastrophic proportions, Defendants have violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL")² and the common law. By flagrantly misrepresenting the efficacy of its own products and impermissibly minimizing the risks associated with opioid usage, Plaintiff and

Plaintiff has not taken poetic license in labeling the current prescription opioid crisis plaguing the United States as "catastrophic." Drug overdose is now the leading cause of accidental death in the United States, with 52,404 such deaths reported in 2015. Of those deaths, prescription opioids accounted for 20,101, or approximately one death every 26 minutes. In 2014, 10.3 million persons reported using prescription opioids nonmedically (i.e., using medications that were either not prescribed, or which were taken for the experience or sensation that they caused), and nearly 2,500 Pennsylvanians died from drug overdoses. In Philadelphia County, alone, there were approximately 46 drug-related deaths for every 100,000 people in 2015. This unprecedented spike in overdose deaths tellingly dovetails with equally outrageous increases in opioid prescriptions: the overdose death rate in 2008 was nearly four times the same rate in 1999, while sales of prescription opioids in 2010 were four times the same rate in 1999. In 2014, alone, more than 240 million prescriptions were written for opioid pharmaceuticals nationwide (or, more than enough for every man, woman, and child in the country to have their own personal supply of pills). Even more troublingly, four out of every five new heroin users reported that their use of illicit narcotics began by abusing prescription opioids, and there is mounting evidence that abuse of prescription opioids is contributing to heroin use and addiction. See, e.g., Wilson M. Compton, M.D., et al., "Relationship between Nonmedical Prescription-Opioid Use and Heroin Use," N. ENGL. J. MED. 374:2, at 160-61 (January 14, 2016) ("Available data indicate that the nonmedical use of prescription opioids is a strong risk factor for heroin use. . . . The transition from nonmedical use of prescription opioids to heroin use appears to be part of the progression of addiction . . . primarily among persons with frequent nonmedical use and those with prescription opioid abuse or dependence."). PURDUE's overzealous and fraudulent marketing of prescription opioids (in particular, OxyContin) to doctors and patients contributed—and is still contributing—to an ongoing public health crisis. See, e.g., Christopher Ingraham, "How an 'abuse-deterrent' drug created the heroin epidemic," THE WASHINGTON POST, (January 10, 2017), available at https://goo.gl/qMLQK6 (citing a study conducted by the National Bureau of Economic Research that the reformulation of OxyContin to be "abuse-deterrent" was responsible for <u>80 percent</u> of the increase in heroin-related mortalities since 2010). ² 73 P.S. §§ 201-1, et seq.

the Class have suffered ascertainable losses as a result of its conduct as more specifically set forth below.

THE PARTIES

- 2. Plaintiff is the PFTHW, with an office and principal place of business located at 1816 Chestnut Street, Philadelphia, Pennsylvania 19103. The PFTHW provides various benefits for members, retirees, spouses, and dependents of the Philadelphia Federation of Teachers Local 3. These benefits include, but are not limited to, a range of prescription drug benefit plans. Pursuant to the administration and management of these various plans and at all times relevant hereto, the PFTHW, through managed care administrators and others, purchased prescription drugs for its members, retirees, spouses, and dependents, or reimbursed the aforesaid individuals for their prescription drug purchases.
- 3. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of the state of Delaware and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.
- 4. Defendant Purdue Pharma Inc. is a corporation incorporated under the laws of the state of Delaware and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.
- 5. Defendant Purdue Frederick Company, Inc. is a corporation incorporated under the laws of the state of Delaware and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.
- 6. Defendant Abbott Laboratories, Inc. is a corporation incorporated under the laws of the state of Illinois and with its principal place of business and corporate headquarters located at 100 Abbott Park Road. Abbott Park, Illinois 60064.

- 7. At all times relevant hereto, Defendants³ have been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County, throughout Pennsylvania, and nationally, including the following products:
 - a. OxyContin (oxycodone hydrochloride extended release): Schedule II opinion agonist⁴ tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."
 - b. **MS Contin** (morphine sulfate extended release): Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."
 - c. **Dilaudid** (hydromorphone hydrochloride): Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."
 - d. **Dilaudid-HP** (hydromorphone hydrochloride): Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."
 - e. **Butrans** (buprenorphine): Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment

³ Defendant ABBOTT entered in to a co-promotion agreement with Defendant PURDUE in 1996. Defendant ABBOTT actively marketed Purdue Opioids pursuant to that agreement from 1996 to 2002. Thereafter, Defendant ABBOTT received residual payments on the sale of Purdue Opioids until 2006.

⁴ While an opioid "agonist" activates opioid receptors in the human body, opioid "antagonists" block the same opioid receptors. Both opioid agonists *and* antagonists may be used in the therapeutic treatment of pain, while antagonists can also be useful in countering the effects of opioid agonist overdoses.

- options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."
- f. Hysingla ER (hydrocodone bitrate): Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.
- 8. At all times relevant hereto, Defendants through their corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed OxyContin, MS Contin, Dilaudid, Dilaudid-HP, Butrans, and Hysingla ER (hereinafter, referred to collectively as the "Purdue Opioids") throughout the United States, and to citizens of the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the PFTHW, and their members, retirees, spouses, and dependents.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties and due to the federal question raised in Count V, infra. See, e.g., 18 U.S.C. § 1961, et. seq. and 28 U.S.C. § 1332(a)(2). Plaintiff is a citizen of, and has its principal place of business in, the Commonwealth of Pennsylvania. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of the state of Delaware and with its principal place of business and corporate headquarters located in Connecticut. Defendants Purdue Pharma Inc. and Purdue Frederick Company, Inc. are corporations incorporated under the laws of the state of Delaware and with their principal place of business and corporate headquarters located in Connecticut.

Laboratories, Inc., is a corporation incorporated under the laws of the State of Illinois, with its principal place of business also in Illinois.

- 10. Personal jurisdiction exists over Defendants in the Commonwealth of Pennsylvania due to the general and specific contacts they maintain in the United States. Defendants maintain those contacts presently and did so at all times material to this action. The amount in controversy exceeds \$75,000.
- 11. This Court additionally has subject matter over this action pursuant to the Class Action Fairness Act. See, e.g., 28 U.S.C. § 1332(d). Upon information and belief, Plaintiff avers that there are more than 100 putative class members, who are (or were) citizens of the Commonwealth of Pennsylvania at all times relevant hereto, and the Defendants are each citizens of another state. The aggregate of the Class Members' claims is more than \$5 million dollars, exclusive of interests and costs.
- 12. Venue is proper in this District pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction, wherein Defendants also conduct substantial business.

FACTUAL BACKGROUND

13. The term "opioid" refers to and includes all natural, synthetic, and semi-synthetic substances that bind to and interact with the opioid receptors in the human brain.⁵ This Class Action primarily implicates a specific subclass of opioids known as "opioid

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⁵ See, e.g., Freye, Enno, "Part II. Mechanism of action of opioids and clinical effects," Opioids in Medicine: A Comprehensive Review on the Mode of Action and the Use of Analgesics in Different Clinical Pain States, p. 85 (2008) ("Opioid is a general term that includes naturally occurring, semi-synthetic, and synthetic drugs, which produce their effects by combining with opioid receptors").

agonists," which principally have an analgesic effect when taken for therapeutic purposes (i.e., the relief of pain). All of the Purdue Opioids listed are opioid agonists.

- 14. Pharmacologically, the Purdue Opioids interact with opioid receptors located in the brain and spinal cord, and are an effective option in the treatment of acute short-term pain (e.g., surgery, traumatic injuries, and/or cancer) and the provision of end-of-life care. However, the Purdue Opioids are essentially the same as narcotics like heroin and carry dangerously high risks for abuse, development of dependence/tolerance, and addiction. The abuse (and even the mere use) of opioids is also associated with the potential for severe physical side effects, including respiratory depression, coma, and death.
- 15. Individuals using and/or abusing opioids in the long-term can eventually develop tolerance (and, therefore, require ever-increasing dosages to continue to achieve the desired analysesic effect).¹² The diminishing returns of treatment also make overdoses much

⁶ There are also "opioid antagonists," "opioid peptides," and "opioid receptors." Id. at 85.

⁷ See, e.g., Nathaniel Katz, "Opioids: After Thousands of Years, Still Getting to Know You," 23(4) CLIN J. PAIN 303 (2007); Roger Chou, et al., "Research Gaps on Use of Opioids for Chronic Noncancer Pain," 10(2) J. PAIN 147 (2009).

⁸ See, e.g., Wilson M. Compton, M.D., et al., "Relationship between Nonmedical Prescription-Opioid Use and Heroin Use," N. ENGL. J. MED. 374:2, at 155 (January 14, 2016) ("Heroin is pharmacologically similar to prescription opioids.").

⁹ See, e.g., Wilson M. Compton & Nora D. Volkow, "Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies," 81(2) DRUG & ALCOHOL DEPENDENCE 103, 106 (2006) ("[A] potential side effect from chronic use [of opioids] can be abuse and addiction In fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena.").

As used throughout this Class Action Complaint, the term "addiction" refers to the full spectrum of "substance abuse disorders" identified in the authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) ("DSM-V"), and encompasses behavior ranging from abuse/misuse of drugs, through physical and/or mental dependence, to addiction.

¹¹ See, e.g., Letter from Janet Woodcock, M.D. to Andrew Kolodny, MD RE: Docket No. FDA-2012-P-0818 (September 10, 2013), at 2, available at https://goo.gl/oT4pRw ("Even proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.").

¹² See, e.g., Mitchell H. Katz, "Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith," 170(16) ARCHIVES OF INTERNAL MED. 1422 (2010) (describing doses that are "frighteningly high").

more insidiously common,¹³ and even individuals who ultimately cease using opioids also risk severe withdrawal symptoms.

- 16. Thus, opioids have been regulated as controlled substances for decades.¹⁴
- 17. Although opioids are considered generally effective in the treatment of short-term conditions and pain, no controlled studies have ever concomitantly established the efficacy or safety of using opioids in the treatment of chronic pain or other long-term medical conditions. Indeed, medical and pharmacological research and studies produced during the 1970s and 1980s indicated a growing scientific consensus that opioids should be discouraged (or even prohibited) in the treatment of chronic pain. An article written in 1994 best encapsulates the even-then-prevailing attitudes regarding the long-term use of opioids:

The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by eh desire to maintain analgesic effects, avoid withdrawal, and perpetuated reinforcing psychic

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¹³ See, e.g., "Opioid Overdose," CENTERS FOR DISEASE CONTROL AND PREVENTION, available at https://goo.gl/6LSx6v (last accessed September 3, 2017) (reporting that opioid-related overdoses accounted for more than 33,000 deaths in 2015, nearly half involving prescription drugs).

¹⁴ Opioids have been regulated as a controlled substance since the passage of the Controlled Substances Act ("CSA") in 1970, which imposed a hierarchy of restrictions on the distribution of drugs based on their medicinal value, the likelihood that use of the drug will lead to addiction and/or abuse, and overall safety. All of the Purdue Opioids are Schedule II substances, except for Butrans which is a Schedule III substance. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse when compared to Schedule II drugs, but their abuse may lead to moderate or low physical dependence or high psychological dependence.

effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.¹⁵

- 18. Continuing through until the present, medical evidence continues to establish that the long-term use of opioids produces rapidly diminishing analgesic benefits (if any)¹⁶ and diminishes patients' overall health.¹⁷
- 19. In March 2016, the Centers for Disease Control and Prevention ("CDC") stated unequivocally: "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least one year later . . . Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury."¹⁸
- 20. Prior to the acts of Defendants complained of herein¹⁹ "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids."²⁰

¹⁵ Russell K Portenoy, "Opioid Therapy for Chronic Nonmalignant Pain: Current Status," 1 PROGRESS IN PAIN RES. & MGMT. 247 (1994).

¹⁶ See, e.g., Andrea D. Furlan, et al., "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) CAN. MED. ASS'N J. 1589 (2006); Eriksen J., et al., "Critical issues on opioids in chronic non-cancer pain," 125 PAIN 172, 172-79 (2006) (concluding that chronic pain patients taking opioids self-scored themselves lower in terms of body pain, physical function, mental function, social function, and vitality compared to non-opioid patients); Dillie K.S., et al., "Quality of life associated with daily opioid therapy in a primary care chronic pain sample," 21 J. AM. BD. FAM. MED. 108, 108-17 (2008).

¹⁷ See, e.g., Andrea Rubenstein, "Are we making pain patients worse?" SONOMA MEDICINE (Fall 2009), available at https://goo.gl/Y5gQ93 ("[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.").

Deborah Dowell, M.D., et al., "CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016," CENTERS FOR DISEASE CONTROL AND PREVENTION, (March 18, 2016), available at https://goo.gl/SUXyg7. In fact, these guidelines definitively undercut PURDUE's misrepresentations regarding the alleged efficacy of opioids in the treatment of long-term, chronic pain: "[P]hysical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion." Id. (emphasis added).

¹⁹ PURDUE's conduct has been under intense regulatory scrutiny for more than a decade. In 2007, PURDUE entered into a Corporate Integrity Agreement (hereinafter, "PURDUE CIA") with the Office of the Inspector General of the U.S. Department of Health and Human Services and paid a \$635 million settlement to the

- 21. However, the widely recognized therapeutic limits discussed above also had a secondary (and, from the perspective of Defendants, an unwanted) effect: significantly limiting the available Patient Population Market for the use of opioids. Put simply, the widely accepted understanding that opioids were ineffective (and, in fact, dangerous) when used to treat long-term conditions and/or chronic pain was an economically inconvenient truth that Defendants wished to alter for purely pecuniary purposes (*i.e.*, profit).
- 22. Beginning in the late 1990s, and continuing until the present, Defendants engaged in a deceptive, unfair, and misleading marketing campaign in order to reverse the popular and medical understanding that opioids were inappropriate for the treatment of chronic pain-related conditions such as common aches and pains, headaches, backaches, etc. As a result of Defendants' systematic efforts, the use of opioids to treat chronic pain and long-term medical conditions (hereinafter, "chronic opioid therapy") is commonplace.
- 23. To accomplish this wholesale reversal in medical and popular opinion, Defendants undertook the following initiatives either directly, or through their agents, employees, servants; and/or representatives:

United States government for marketing misconduct. The PURDUE CIA, amongst other things, requires PURDUE to fairly and accurately market its products and regularly report on its compliance. Within a few days of that settlement, PURDUE also entered into a Consent Judgment in a separate criminal action brought by the Attorneys General of twenty-seven (27) separate state governments (including Pennsylvania), which placed equally broad obligations upon PURDUE to market its products accurately and fairly. See, e.g., Consent Judgment, Commonwealth of Pennsylvania v. Purdue Pharma, Inc., et al., Case No. 238 M.D. 2007 (Pa. Commw. Ct., May 3, 2007) (requiring PURDUE to not make "false, misleading, or deceptive" marketing claims regarding the Purdue Opioids and OxyContin, including claims that misrepresent or minimize the attendant risks for abuse, addiction, physical dependence, and any other reliance upon "misinformation"). Moreover, on April 18, 2013, the United States Department of Health and Human Services issued a determination that the original formulation of OxyContin was withdrawn by PURDUE as a result of safety and effectiveness concerns. See, e.g., Determination That the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn From Sale for Reasons of Safety or Effectiveness, 78 FED. REG. 23273-75 (April 18, 2013) ("Based on the totality of the data and information available to the Agency at this time, FDA concludes that the benefits of original OxyContin no longer outweigh its risks."). ²⁰ Igor Kissin, "Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected

safety?", 6 J. PAIN RESEARCH 513, 514 (2013).

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- developing and disseminating seemingly truthful, purportedly educational materials and advertisements that misrepresented the risks, benefits, and superiority of Purdue Opioids when used in chronic opioid therapy;
- b. deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the long-term use of Purdue Opioids when used in chronic opioid therapy;
- c. recruiting prescribing physicians as paid speakers on behalf of Purdue Opioids in order to secure "brand loyalty" for Purdue Opioids and extend Defendants' reach to those physicians' peers;
- d. funding, assisting, encouraging, and/or directing certain physicians to not only deliver scripted talks, but to draft misleading studies, present deceptive and misleading continuing medical education programs ("CMEs"), and serve on the boards and committees of professional societies and patient advocacy groups that promulgate guidelines supporting chronic opioid therapy in order to ensure support for the use of Purdue Opioids (hereinafter, "key opinion leaders" or "KOLs"); and
- e. funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (hereinafter, "Front Groups") that developed educational materials and treatment guidelines that were distributed by Defendants, which urged physicians to prescribe (and patients to use) Purdue Opioids in chronic opioid therapy.
- 24. Defendants' misleading course of conduct that is generally described above was pervasive and focused primarily on the promotion of OxyContin (although upon information and belief, Defendants' marketing efforts extended to and included *all* of the Purdue Opioids identified above).
- 25. Defendant ABBOTT joined forces with Defendant PURDUE in 1996 through a co-promotion agreement. ABBOTT had a significant sales force already working in hospitals around the country and maintained ongoing relationships with doctors and pain treatment teams. Through the co-promotion agreement, ABBOTT devoted 300 sales representatives to OxyContin sales, which matched the sales force established by PURDUE.

- 26. ABBOTT actively marketed OxyCntin from 1996 though 2002 and then continued to participate with PURDUE through 2006. With ABBOTT'S help, sales of OxyContin went from \$49 million in the first full year on the market to \$1.6 billion in 2002. Over the life of the agreement, Abbott was paid hundreds of millions of dollars.
- 27. ABBOTT heavily incentivized its sales force to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. Top performers were given fanciful titles such as "Wizard of OxyContin" and "Supreme Sovereign of Pain Management." The head of pain care sales, Jerry Eichhorn, was known as the "King of Pain" and signed memos as simply "King."
- 28. In an internal memo, ABBOTT sales staff were instructed that if a doctor was concerned about the euphoria a patient experienced on the shorter-acting painkiller Vicodin, they should tell the physician "OxyContin has fewer such effects." Yet another memo told sales representatives to highlight the "less abuse/addiction potential" of OxyContin which could be taken just twice a day because of the time-release design. Representatives of ABBOTT were trained to only discuss potential abuse issues if a doctor brought it up and to inform them that "street users" were abusing the drug, and not "true pain patients."
- 29. ABBOTT utilized many of the same techniques as PURDUE with direct-tophysician marketing including food, gifts, and influence peddling, techniques that netted ABBOTT a huge portion of the profits from Purdue Opioid sales.
- 30. The sales forces of PURDUE and ABBOTT worked in tandem, holding regular joint strategy sessions, alternating meeting locations between Abbott's headquarters and Purdue's headquarters.

- 31. Upon information and belief, OxyContin is the best-selling Purdue Opioid nationally and in Pennsylvania and Philadelphia. Overall, the purpose of Defendants' actions described above and throughout this Class Action Complaint was to encourage patients to request and doctors to prescribe OxyContin and the other Purdue Opioids, and to promote chronic opioid therapy.
- 32. Defendants' support and creation of deeply misleading and purportedly educational materials included statements and advertisements in scholarly journals,²¹ books,²² pamphlets and other documents geared towards doctors, patients, and potential patients,²³ and other materials that were put forth as nominatively educational and scientific (but, in fact, fly in the face of established medical science).²⁴ Defendants' marketing efforts also

²¹ See, e.g., Jane Porter & Hershel Jick, "Addiction Rare in Patients Treated with Narcotics," 302(2) NEW ENG. J. MED. 123 (January 10, 1980) ("We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction."). This letter to the editor has been widely discredited since its publication, yet PURDUE explicitly trained its sales representatives to claim that the risk of addiction among patients being treated with the Purdue Opioids was less than one (1) percent, citing, amongst other erroneous sources, the letter from Porter and Jick as authoritative justification. See, e.g., Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99(2) AM. J. PUB. HEALTH 221 (2014) (, available at https://goo.gl/JqWcGA. See also, e.g., C. Peter N. Watson, et al., "Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy," 105 PAIN 71 (2003) (citing the Porter & Jicks letter to support the notion that OxyContin is not typically addictive). Furthermore, PURDUE caused a separate study that they had sponsored which ultimately concluded that OxyContin had addiction rates between 8 and 13 percent to be buried in headache-specific literature, so as to minimize its impact. See, e.g., Lawrence Robbins, "Long-Acting Opioids for Severe Chronic Daily Headache," 10(2) HEADACHE QUARTERLY 135 (1999); see also, e.g., Lawrence Robbins, "Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache," 19 HEADACHE QUARTERLY 305 (1999).

²² See, e.g., Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide, (2007) (produced by the Federation of State Medical Boards with significant support from PURDUE and other opioid manufacturers).

²³ In 2012, PURDUE disseminated a mailer titled "Pain Vignettes" that contained purported individual testimonies of OxyContin patients whose overall functionality and quality of life had been improved by a regular prescription of OxyContin. These claims fly in the face of the well-established medical consensus that long-term use of opioids does not improve life quality or overall functionality.

²⁴ As a mere example, PURDUE ran an OxyContin advertisement in a 2005 issue of the *Journal of Pain* that promoted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a dramatization of a man and young boy fishing, with the epithet: "There Can Be Life With Relief." This depiction falsely implied that OxyContin is effective at both long-term pain relief and functional improvement of overall health—claims that are wholly unsubstantiated by some 40 years of medical literature.

included non-branded advertising,²⁵ journal inserts geared towards physicians,²⁶ and a significant online presence.²⁷ Defendants also conducted direct solicitation efforts that included phoning doctors/prescribers directly. Upon information and belief, Defendants continued to contact doctors/prescribers in support of Purdue Opioids even after those same individuals/entities were place on "do not call" lists.

33. In addition to these indirect marketing efforts, Defendants also engaged in direct misleading marketing representations through its sales representatives,²⁸ including

²⁵ For example, PURDUE nationally published and distributed a nominally educational pamphlet geared towards law enforcement and prescribers titled "Providing Relief, Preventing Abuse," which both impermissibly focused on the allegedly isolated incidents of OxyContin being abused via injection, while ignoring other common signs of addictive behavior (*i.e.*, asking for early refills or increased dosages). Moreover, this pamphlet emphasized the scientifically bereft term "pseudoaddiction" to explain potential drugseeking behavior (and omitting that the concept of "pseudoaddiction" has been roundly rejected by the medical and scientific communities). PURDUE's nefarious invocation of the term "pseudoaddiction" suggests that addictive behavior can be solved by "completely" treating a patient's underlying chronic pain (*i.e.*, prescribing more opioids).

²⁶ PURDUE also regularly advertised in both the *Journal of Pain* and the *Clinical Journal of Pain*, touting false claims suggesting that OxyContin was convenient for both patients and doctors because the drugs were effective for twelve (12) hours at a time (*i.e.*, Q12H). In reality, an allegedly Q12H dose of OxyContin does <u>not</u> provide the complete twelve (12) hours of relief that PURDUE claimed, but instead required consistently higher and more frequent dosages to achieve the same level of pain relief in the long-term (*i.e.*, in the treatment of so-called "chronic" conditions). Upon information and belief, Plaintiff asserts that Q12H OxyContin was much more rapidly absorbed (*i.e.*, depleted) than advertised by PURUDE, which was meant to increase the necessary doses required to provide adequate pain relief.

²⁷ In particular, PURDUE sponsored, supported, and/or maintained at least two separate websites: In the Face of Pain and Partners Against Pain. These unbranded websites continued to press PURDUE's major argument that the use of Purdue Opioids (and OxyContin, in particular) were somehow essential to the effective treatment of chronic pain, and labeled skepticism regarding such uses of opioids as being the result of "inadequate understanding" that leads to "inadequate pain control." In the Face of Pain openly criticized policies that limited access to opioids as being "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors willing to treat their pain (i.e., prescribed opioids). In the Face of Pain was a gateway for deceptive clinical trials, medical information, and deceptive testimony from seemingly neutral "Advocates" who were actually heavily compensated KOLs and/or patients procured and directed by PURDUE. See, e.g., Purdue Pharmaceuticals, "In the Face of Pain® Offers New Tools and Resources to Patients, Caregivers and Healthcare Professionals Advocating for Better Pain Care," (September 22, 2011), available at https://goo.gl/vZGd6v. Similarly, PURUDE utilized its website Partners Against Pain to digitally distribute its 2005 pamphlet titled "Clinical Issues in Opioid Prescribing," which claimed that "illicit drug use and deception" did not indicate an underlying addiction, but merely meant that the patient's pain was undertreated: "Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated." In other words, prescribers confronted with potentially addictive behavior from patients should prescribe more opioids, and turning addiction into nothing more than an excuse to sell everincreasing amounts of Purdue Opioids.

²⁸ PURDUE went so far as to target individual prescribers and track their prescribing habits. These efforts included a secret monitoring program that, over the course of nine years, identified some 1,800 doctors whose

spoken representations and the distribution and publication of promotional and educational materials. PURDUE employed some 250 sales representatives in 2007 alone, of whom a full 150 were entirely devoted to promoting OxyContin. In 2014, alone, PURDUE spent \$108 million on such direct sales efforts. Upon information and belief, Plaintiff avers that those direct sales materials, representations, and solicitations also misrepresented the efficacy of Purdue Opioids and the risks associated with chronic opioid therapy.

- 34. Overall, these marketing efforts ultimately had a substantial and pervasive impact on the regularity with which doctors prescribed OxyContin and the other Purdue Opioids to their patients.²⁹ Moreover, PURDUE has been ramping up its promotional efforts in recent years—between 2007 and 2014, PURDUE's quarterly promotional spending increased from under \$5 million to more than \$30 million.
- 35. Defendants also recruited, trained, supported, paid, and utilized specialists in pain medicine, high prescribers of Purdue Opioids, and other similarly situated physicians to serve as both paid speakers and KOLs³⁰ in order to win influence and prestige for the

prescribing habits demonstrated a high probability that they were writing prescriptions of Purdue Opioids for addicts and drug dealers. A separate lawsuit filed in the Superior Court of the State of Washington for Snohomish County details that PURDUE was readily able to identify doctors that were operating so-called "pill mills," and took no action to shut down their proverbial "gold mines." See, e.g., Complaint, City of Everett v. Purdue Pharma, L.P., et al., Case No. 17-2-00469-31, at ¶¶ 46-61 (January 19, 2017).

²⁹ See, e.g., Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99(2) Am. J. Pub. Health 221 (2014) (identifying a correlation between the increase in OxyContin prescriptions from 670,000 in 1997 to 6.2 million in 2002 and PURDUE's doubling of its sales force and trebling of its annual sales calls), available at https://goo.gl/gp3qQh.

³⁰ The precise nature and complete extent of Defendants' cultivation of medical KOLs is unknown to Plaintiff and the Class, but is uniquely known to Defendants. Upon information and belief, Defendants approached and retained numerous KOLs in its marketing of the Purdue Opioids and utilized them in the manner described in this Class Action Complaint. Prominent examples of these KOLs include Dr. David Haddox, Dr. Russell Portenoy and Dr. Lynn Webster, all of whom are substantively cited throughout. In particular, Dr. Haddox began as a paid PURDUE speaker and ultimately became PURDUE's Vice President of Risk Management—he was responsible for coining the misleading phrase "pseudoaddiction," although it was popularized by Drs. Portenoy and Webster. To his credit, Dr. Portenoy has since admitted that his actions were responsible for spreading "misinformation" and that he "gave innumerable lectures in the late 1980s and 90s about addiction that weren't true." Thomas Catan & Evan Perez, "A Pain-Drug Champion Has Second Thoughts," The WALL STREET JOURNAL (Dec. 17, 2012). Similarly, Dr. Webster was responsible both for the development of a cursory (and ineffective) diagnostic tool (i.e., a five-question, one-minute questionnaire) that

Purdue Opioids within the medical community. Upon information and belief, Defendants' paid speakers and KOLs adhered to PURDUE's dictated "messaging." PURDUE's efforts included the creation, distribution, and presentation of medical supplements and CME materials that misrepresented the nature of Purdue Opioids and chronic opioid therapy,³¹ and similar initiatives.

36. Defendants have also utilized, co-opted, appropriated, infiltrated, usurped and/or created so-called professional and patient advocacy and affinity groups ("Front Groups") to amplify the reach of its illicit marketing activities, including the American Pain Foundation (the "APF"), 32,33 the Federation of State Medical Boards (the "FSMB"), 34 the

was purportedly useful in predicting a person's risk for developing opioid addiction (the "Opioid Risk Tool"). Dr. Webster was also responsible for disseminating, at PURDUE's behest, various materials regarding so-called "pseudoaddiction," a term and "condition" that even Dr. Webster has since admitted "became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept." John Fauber & Ellen Gabler, "Networking Fuels Painkiller Boom," THE MILWAUKEE WISCONSIN JOURNAL SENTINEL (Feb. 19, 2012).

³¹ For example, PURDUE sponsored a 2011 webinar taught by Dr. Lynn Webster titled "Managing Patient's Opioid Use: Balancing the Need and Risk," which instructed doctors that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." This material emphasized the use of ineffectual "tools" like the Opioid Risk Tool developed by Dr. Webster (which relies heavily upon since-discredited concepts, such as "pseudoaddiction"). In February 2012, PURDUE sponsored a CME program titled "Safe Opioid Prescribing," which continued to cite a now-debunked 1980 study that impermissibly misrepresented the dangers of opioid addiction, and also falsely emphasized the "competing public health crisis of undertreated pain and prescription drug use." In October 2012, PURDUE sponsored a CME-eligible program titled "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which recommended that the use of screening "tools," more frequent refills, and switching between different opioid formulations could treat high-risk patients who are showing signs of potentially addictive behavior. PURDUE also sponsored a CME titled Path of the Patient: Managing Chronic Pain in Younger Adults at Risk for Abuse, which suggested that younger chronic opioid therapy patients who are at-risk for addiction may simply be suffering from so-called "pseudoaddiction." Likewise, PURDUE sponsored a series of CMEs titled Overview of Management Options, which were issued by the American Medical Association and suggested that opioid alternatives (i.e., NSAIDs) are dangerous at high doses, but which omitted opioids from similar analysis (despite definitive medical evidence to the contrary).

Defendants exercised tremendous and constant control over the efforts and conduct of the APF, which were explicitly intended and directed to complement and support PURDUE's own marketing efforts. Pursuant to a "Master Consulting Services Agreement" executed on September 14, 2011, PURDUE was granted contractual editorial and administrative oversight over APF's promotional efforts on their behalf, and also gave PURDUE the ultimate power of the purse (i.e., the unilateral right to terminate the agreement at their discretion). PURDUE thereafter, and before, utilized APF to support its misrepresentative and fraudulent marketing efforts in the following ways: (a) hiring an APF consultant to conduct work on the rollout of the Partners Against Pain website; (b) hiring an APF consultant to conduct work and promotion of one of PURDUE's opioid-related projects, Understanding & Coping with Lower Back Pain; (c) obtaining "patient representatives" to provide testimonials on Partners Against Pain; (d) soliciting and/or requiring APF board

American Pain Society (the "APS"), the American Academy of Pain Medicine (the "AAPM"),³⁵ and the American Geriatric Society (the "AGS").³⁶

members (including Dr. Lynn Webster) and other PURDUE KOLs and patients to appear on In the Face of Pain as "champions passionate about making a difference in the lives of people who live with pain" (while in fact the parties were well-compensated for their appearances); (e) requiring APF to cede control of its highly influential Pain Care Forum ("PCF") to PURDUE's in-house lobbyist Burt Rosen so that the group's efforts could be directed solely for PURDUE's benefit; (f) utilizing the PCF to undermine any requirements that prescribers attend CMEs addressing best-practices in the area of chronic opioid therapy; and (g) utilizing the PCF to essentially parrot PURDUE's own misrepresentative marketing campaign, including the following statement: "[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug." "Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Before the S. Committee On the Judiciary," 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Strangely, no medical or scientific support exists for these statements. Moreover, APF's board of directors included PURDUE KOL's Russell Portenoy and Scott Fishman, as well as two other members who received consulting fees or had close connections with PURDUE (Lisa Weiss & Perry Fine).

- 33 PURDUE also collaborated extensively with APF in the publication of various supplements, providing substantial support of the organization, exercising editorial control over content, and taking a substantial role in the variety of misleading and deceptive messages, promotional materials, marketing, and educational products promulgated by APF at the behest, and with the direct support of, PURDUE. These publications included the A Policymaker's Guide to Understanding Pain & Its Management, which was published by APF in 2011 with at least \$26,000 in grant money and extensive direction from PURDUE. The *Policymaker's Guide* flagrantly misrepresented that there were scholarly studies demonstrating that chronic opioid therapy could improve patients' "daily function, psychological health and overall health-related qualify of life," mislabeled potential indicators of dangerous addictive behavior as "pseudoaddiction" that are mere "patient behaviors that may occur when pain is undertreated," falsely claimed that "less than 1 percent of children treated with opioids become addicted," and misstated the dangers associated with continually increasing dosages of Purdue Opioids by claiming that such increased dosages are required to overcome tolerance and is "not necessarily indicative of addiction." The APF also published Treatment Options: A Guide for People Living with Pain in 2007 with significant contributions from PURDUE, which impermissibly minimized the risks of chronic opioid therapy, and denigrated alternative treatment options like NSAIDs by falsely claiming that opioids have "no ceiling dose." The APF also published Exit Wounds, a deceptive and misrepresentative publication aimed at veterans that stated that use of opioids increases functionality and grossly minimized the risks of addiction.
- ³⁴ In concert with pharmaceutical companies including PURDUE, the FSMB created "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" in 1998 and 2004. The Guidelines were thereafter used in 2007 (and thereafter) to create a book titled *Responsible Opioid Prescribing*, which was also produced, disseminated, and popularized in conjunction with, and at the behest of, PURDUE. Overall, these publications represented (and continue to represent) the use of opioids in the treatment of chronic pain as "essential." The publications, and in particular the 2007 book, were widely distributed by the FSMB to state medical boards and practicing doctors. Although the 2012 revision no longer recommends chronic opioid therapy as a "first-line" treatment, it does continue to promote the concept of "pseudoaddiction" and suggests managing opioid addiction risks via PURDUE-created, or PURDUE-supported, "screening tools." Overall and upon information and belief, PURDUE spent approximately \$150,000 to help FSMB distribute *Responsible Opioid Prescribing*.
- ³⁵ Both the APS and the AAPM issued consensus guidelines in both 1997 and 2009 endorsing the use of opioids in the treatment of chronic pain and minimizing the resulting risks of addiction. At the time that both sets of guidelines were issued, substantial portions of the reviewing and authoring members were in the putative service of PURDUE, including Dr. David Haddox and Dr. Russell Portenoy. Although they have since been removed, the 2009 guidelines have been widely publicized, cited, and republished.

- 37. Defendants utilized these third-party professional organizations in a variety of ways, including, but not limited to, publishing and popularizing so-called "guidelines" for the use of opioids for the treatment of chronic pain, publishing and popularizing articles, educational materials, and promotional materials that were supportive of Purdue Opioids and/or chronic opioid therapy, supporting and publicizing the work and viewpoints of paid PURDUE speakers and KOLs, and other material support and marketing aimed at buttressing the illusory legitimacy of Purdue Opioids and chronic opioid therapy.
- 38. Reviewing the conclusions of these Front Groups, such as those described above, is also illustrative when viewed in stark contrast to similar guidance issued by independent professional medical organizations during the same time frame:

The recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, by facilitating it.

[T]herapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fataltieis, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.³⁷

³⁷ Laxmiah Manchikanti, et al., "Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain,"

³⁶ For example, the AGS willingly and in concert with PURDUE created and disseminated guidelines for the use of opioids for treating chronic pain in 2009 ("Pharmacological Management of Persistent Pain in Older Persons"). In particular, the 2009 Guidelines advised, without citation to any authoritative source, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The 2009 Guidelines also advised that the risks of addiction resulting from opioid therapy "are exceedingly low in older patients with no current or past history of substance abuse." See, e.g., "Pharmacological Management of Persistent Pain in Older Persons," 57 J. AM. GERIATRICS SOC'Y 1331, 1339, 1342 (2009). Shockingly, the same document also suggested that "all patients with moderate to severe pain, pain-related functional impairment, or diminished qualify of life due to pain should be considered for opioid therapy." Id.

- 39. These independent medical professionals uniformly argue for fundamentally different opioid-related standards of care than those espoused by PURDUE's and the pharmaceutical industry's front.³⁸
- 40. Defendants essentially created a new market for Purdue Opioids from whole cloth through self-promotion and marketing tactics advocating that, rather than being utterly therapeutically inappropriate, that chronic opioid therapy (and, in particular, the use of Purdue Opioids) was somehow necessary for the compassionate treatment of chronic pain in the medical community. By engaging in the course of conduct described above, Defendants have, and continue to:
 - a. misrepresent and overstate the benefits of chronic opioid therapy;
 - b. misrepresent and overstate the directly promised or implied improvements in patients' function and quality of life from chronic opioid therapy;
 - c. misrepresent and/or fail to disclose the lack of evidence supporting chronic opioid therapy;
 - d. misrepresent, trivialize, and/or obscure the serious risks and potential adverse outcomes associated with chronic opioid therapy, including the risks of addiction, overdose, and death;
 - e. misrepresent and/or overstated the superiority of chronic opioid therapy in comparison to other treatment options, including non-opioid analyssics and physical therapy;
 - f. misrepresent and/or mischaracterize the risks and difficulties associated with opioid withdrawal and/or opioid dependence; and
 - g. misleadingly propagated the concept of "pseudoaddiction" and erroneous prescreening initiatives in order to dishonestly deflect concerns regarding addiction.

³⁸ See, e.g., U.S. DEP'T OF VETERANS AFFAIRS & U.S. DEP'T OF DEFENSE, "Clinical Guidelines on Management of Opioid Therapy for Chronic Pain," (May 2010) available at https://goo.gl/Wxg6B5 (confirming the "lack of solid evidence based research on the efficacy of long-term opioid therapy").

- 41. By utilizing third-parties in order to present its questionable viewpoints and misrepresentative "research," Defendants also created the perception that the misrepresentations regarding Purdue Opioids and chronic opioid therapy described herein was the result of independent, objective research. Thus, it was far more likely to influence the opinions of patients, prescribers, and payors. To date, no reliable scientific data supports the marketing claims advanced by Defendants regarding chronic opioid therapy and Purdue Opioids. In fact, as demonstrated by the discussion above, much scientific research directly refutes Defendants, and Defendants' own KOLs have since abandoned their previous positions.
- 42. Despite Defendants duty to truthfully represent the nature and efficacy of its drugs, these misrepresentations were made purely in service of the pursuit of profit. As a mere snapshot of the lucrative nature of Defendants' activities reveals, PURDUE's national annual sales of OxyContin in 2006 were approximately \$800 million. Thereafter, and since 2009, PURDUE's nationwide sales of OxyContin has increased substantially and fluctuated between approximately \$2.5 billion and \$3 billion, every year.
- 43. Defendants' focus on its market share and profitability callously ignores the truth borne out in the grim statistics of the current "opioid crisis" that is sweeping the country, generally, and Pennsylvania specifically—in 2016, approximately thirteen (13) people died <u>every day</u> from drug-related overdoses, of which 85 percent were opioid-related.³⁹ This reality is at least partially a result of Defendants' marketing activities.⁴⁰

1990 to 2007).

See, e.g., Alicia Victoria Lozano, "Philadelphia No Longer Leads State in Fatal Drug Overdose Rate, But Deaths Continue to Rise in Opioid Epidemic," NBC 10 (July 27, 2017), available at https://goo.gl/SE7HdM.
 See, e.g., Susan Okie, "A Flood of Opioids, a Rising Tide of Deaths," 363 NEW ENGL. J. MED. 1981 (2010) (concluding that opioid overdose deaths and prescriptions for opioids both increased roughly by 10-fold from

- 44. At all times relevant hereto, Defendants took steps to avoid detection of and fraudulently conceal their deceptive marketing and conspiratorial behavior.
- 45. Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. PURDUE and ABBOTT purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.
- 46. While PURDUE was listed as a sponsor of many of the publications described in this Class Action Complaint, it never disclosed its role in shaping, editing, and exerting final approval over their content. PURDUE exerted its considerable influence on these promotional and "educational" materials.
- 47. In addition to hiding its own role in generating the deceptive content, PURDUE manipulated its promotional materials and the scientific literature to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. PURDUE distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support. The true lack of support for PURDUE's deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by Plaintiff and the Class.
- 48. Thus, while the ongoing opioid epidemic in the Commonwealth (and the country, at-large) was evident, Defendants, in furtherance of their marketing strategies, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that Plaintiff and the Class now assert. Plaintiff and the Class were

not alerted to the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

- 49. Through their public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff and the Class of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.
- 50. At all times relevant hereto, Plaintiff hereby avers that Defendants' conduct described above (as well as the conduct of Defendants' employees, agents, KOLs, Front Groups, and any other co-conspirators) was directed at Plaintiff, Class Members, doctors/prescribers, healthcare facilities, patients, and commercial markets located in the Commonwealth of Pennsylvania, generally, and Philadelphia City and County, specifically.
- 51. Upon information and belief, Plaintiff avers that Defendants' course of conduct described above stretches across decades and continues up to the date of the filing of this Class Action Complaint.

CLASS ACTION ALLEGATIONS

52. The Class claims all derive directly from a single course of conduct by Defendants. Defendants engaged in uniform and standardized conduct toward the Class. They did not differentiate, in degree of care or candor, their actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief set forth below, the same legal standards under Pennsylvania and/or federal law govern. Accordingly, Plaintiff brings this lawsuit as a Class Action on their own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Federal Rule of Civil Procedure 23. This action satisfies the numerosity,

commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

53. Plaintiffs seek to certify a class defined as follows:

All entities that are citizens of the Commonwealth of Pennsylvania that, for purposes other than resale, purchased, reimbursed and/or paid for all or part of the cost of the Purdue Opioids from 1997 through the date of entry of any class certification order (the "Class Period"). Such entities include, but are not limited to, all self-funded employer plans, private insurance providers, managed care organizations, insurance companies, employee benefit plans, health and welfare funds, union plans, workers' compensation entities, HMOs, PPOs, entities with self-funded plans, private entities paid by any Commonwealth of Pennsylvania governmental agency entity (including the Commonwealth of Pennsylvania's Medicaid Program), and any other entity who is a party to a contract, issuer of a policy, or sponsor of a plan, and is at risk, under such-contract, policy or plan, to pay or reimburse all or part of the cost of the cost of prescription drugs dispensed to covered natural persons.

- 54. Plaintiffs seek to certify the above defined Class for all causes of action alleged herein.
- 55. The prerequisites to maintaining a class action under Fed. R.Civ. P. 23(a) and (b) are met for the following reasons:
 - A. <u>Numerosity</u>: Upon information and belief, Plaintiffs state that there are at least 100 entities who paid for, who paid reimbursements to its members for purchases of, the Purdue Opioids in the course of administering their respective health care plan. Therefore, the proposed Class is so numerous that joinder of all individual members is impractical.
 - B. <u>Commonality</u>: Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to Plaintiffs and Class Members are:
 - i. Whether and the extent to which the Purdue Opioids and chronic opioid therapy are effective in the

- manners claimed and asserted by Defendants' advertising;
- ii. Whether and the extent to which Defendants' claims regarding the Purdue Opioids and chronic opioid therapy are supported by competent scientific evidence;
- iii. Whether and the extent to which Defendants misrepresented or obfuscated the characteristics, uses, and benefits associated with the Purdue Opioids, specifically, and chronic opioid therapy, generally, which had the effect of causing significant confusion;
- iv. Whether and the extent to which Defendants misrepresented the standard, quality, and/or grade of the Purdue Opioids;
- v. Whether and the extent to which Defendants misrepresented the availability, efficacy, and risks associated with alternatives to chronic opioid therapy;
- vi. Whether and the extent to which Defendants failed to comply with the written guarantees and/or warrantees given to Plaintiff, the Class, their members, and/or prescribing doctors regarding the efficacy of the PURUDE Opioids and the risks associated with chronic opioid therapy;
- vii. Whether and the extent to which Defendants' conduct described throughout this Class Action Complaint created a significant likelihood of confusion and/or misunderstanding regarding the potential and proper uses of PURUDE Opioids, specifically, and chronic opioid therapy, generally.
- viii. Whether and the extent to which Defendants have been unjustly enriched at the expense of Plaintiff and the Class;
- ix. Whether and the extent to which Defendants have breached the implied warranty of merchantability for PURDUE's marketing and sale of Purdue Opioids;
- x. Whether and the extent to which Defendants participated in a civil conspiracy along with KOLs

- and Front Groups towards the common purpose of deceptively and misleadingly promoting Purdue Opioids for use in chronic opioid therapy;
- xi. Whether Defendants violated 18 U.S.C. § 1961, et seq.; and
- xii. Whether and the extent to which Defendants engaged in a pattern of racketeering activity.
- C. <u>Typicality</u>: Plaintiff's claims are typical of the claims of Class Members because each entity either directly paid for, or reimbursed its members for purchases of, Purdue Opioids as a result of the misrepresentations regarding the efficacy of chronic opioid therapy that were advanced, supported, and abetted by Defendants. As such, the claims or defenses of the representative parties are typical of the claims or defenses of the class.
- D. <u>Adequacy of Representation</u>: Plaintiff will fairly and adequately protect the interests of Class Members. Plaintiff has retained counsel competent and experienced in complex class action litigation and with adequate resources to assure the interests of the Class will not be harmed. The named Plaintiff is typically situated and has no conflict of interest with the Class as a whole.
- E. Class Action Maintainable under Rule 23(b)(2): A class action is appropriate because common questions of law and fact predominate over any individual questions affecting only individual members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated entities to prosecute their common claims in a single form simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, Defendants will remain free from responsibility for its course of deceptive and misrepresentative conduct, and will be allowed to retain the proceeds that it obtained from deceiving Plaintiff and the members of the Class into paying exorbitant amounts of money for unnecessary and ineffectual medication. Without class treatment, Plaintiff and similar entities will be forced to conduct protracted, piecemeal litigation that might risk establishing conflicting standards of conduct and/or determinations.

- F. <u>Class Action Maintainable Under Rule 23(b)(3)</u>: By flagrantly misrepresenting and misstating the efficacy of the Purdue Opioids and chronic opioid therapy, the Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making the claims for monetary, injunctive, and declaratory relief sought herein the appropriate remedies for the Class.
- G. <u>Ascertainability</u>: The Class Members are ascertainable as both Defendants can identify every single class member from their respective contemporaneously kept medical & financial records, and plaintiff-members, themselves, can determine the amount of money spent on Purdue Opioids during the relevant time period. Accordingly, nothing more than mere ministerial acts on the part of Defendants and the potential Class Members will be necessary to ascertain all potential Class Members.
- 56. In this action, the PTFHW seeks all appropriate and available relief from Defendants for their misrepresentations and deceptive conduct in the course of promoting the sale of Purdue Opioids, including, but not limited to, the false efficacy of chronic opioid therapy, generally and of OxyContin specifically.

COUNT I

VIOLATION OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW

- 57. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.
- 58. This cause of action is brought pursuant to the UPTCPL, which provides protection against unfair or deceptive acts or practices in the conduct of any trade or commerce as defined in 73 P.S. § 201-2(4)(i)-(xxi). See, e.g., 73 P.S. § 201-3.
- 59. Plaintiff and the Class are "persons" as defined by the relevant section of the UTPCPL. See, e.g., 73 P.S. § 201-2(2) (including "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entities").

- 60. At all times relevant hereto, Plaintiff purchased Purdue Opioids on behalf of the PFTHW members, spouses, dependents, and/or retirees from Defendants for personal, family or household purposes as defined by the relevant section of the UTPCPL. See, e.g., 73 P.S. § 201-9.2.
- 61. At all relevant times, Plaintiff and the Class suffered an "ascertainable loss" of money as defined by the UTPCPL. See, e.g., 73 P.S. § 201-9.2.
- 62. At all relevant times, the transactions between Plaintiff, the Class and Defendants constituted "trade or commerce" as defined by the UTPCPL. See, e.g., 73 P.S. §§ 201-2(3) and 201-3.
- 63. Defendants' ongoing campaign of misinformation, confusion, misrepresentation, and deception violates Sections 201-2(4)(v), (vii), (viii), (xiv), and (xxi) of the UTPCPL in at least the following respects:
 - a. Defendants' conduct described throughout this Class Action Complaint misrepresented the characteristics, uses, and benefits associated with the prescription, purchase, and/or use of Purdue Opioids by impermissibly minimizing the risks associated with utilizing Purdue Opioids (e.g., addiction, serious bodily injury, and/or death) and greatly overstating the potential benefits (e.g., claims regarding increased functionality);⁴¹
 - b. Defendants' conduct described throughout this Class Action Complaint misrepresented that Purdue Opioids are of a particular standard, quality, or grade (*i.e.*, safe for use in the therapeutic fashions described by Defendants) when, in reality, they are of a much different standard, quality, or grade (*i.e.*, gravely dangerous in the context of chronic opioid therapy);⁴²
 - c. Defendants' conduct described throughout this Class Action Complaint misrepresented the availability, efficacy, and risks associated with alternatives to chronic opioid therapy (e.g., physical therapy, NSAIDs);⁴³

⁴¹ See, e.g., 73 P.S. § 201-2(4)(v).

⁴² See, e.g., 73 P.S. § 201-2(4)(vii).

⁴³ See, e.g., 73 P.S. § 201-2(4)(viii).

- d. Defendants' conduct described throughout this Class Action Complaint failed to comply with the written guarantees and/or warrantees given to Plaintiff, the PTFHW members, spouses, dependents, and/or retirees, or prescribing doctors regarding the efficacy of the Purdue Opioids and the risks associated with chronic opioid therapy (e.g., marketing materials supported, produced, and/or distributed by Defendants);⁴⁴ and
- e. Defendants' conduct described throughout this Class Action Complaint created a significant likelihood of confusion and/or misunderstanding regarding both the potential and proper uses of Purdue Opioids, specifically, and chronic opioid therapy, generally.⁴⁵
- 64. Overall, Defendants misrepresented, deceived, concealed, omitted, and/or failed to inform Plaintiff PTFHW, its members, spouses, dependents, and retirees, and the doctors prescribing Purdue Opioids that the use of Purdue Opioids was neither safe nor efficacious in the treatment of chronic pain or other long-term medical conditions. Defendants' impermissible behavior is well-described throughout this Class Action Complaint, and includes direct and indirect (i.e., carried out by Defendants' agents, employees, representatives, paid speakers, servants, and/or KOLs) actions: (a) concealing, deceiving, obfuscating, or otherwise misrepresenting the results of definitive medical studies and persuasive empirical research demonstrating the dangers associated with chronic opioid therapy and Purdue Opioids; (b) deliberately misrepresenting and/or deceptively describing the efficacy of Purdue Opioids (in particular, OxyContin) at managing chronic pain and other long-term medical conditions; (c) publishing or causing to be published various materials containing false or deceptive information upon which physicians, Plaintiff, and Plaintiff's members, spouses, dependents, and retirees relied upon in choosing to prescribe, pay for, or take Purdue Opioids when safer, more effective, and less expensive treatments

⁴⁴ See, e.g., 73 P.S. § 201-2(4)(xiv).

⁴⁵ See, e.g., 73 P.S. § 201-2(4)(xxi).

were available for the management of chronic pain and other long-term medical conditions; and (d) otherwise creating confusion and uncertainty regarding the safe, recommended, and medically sound therapeutic uses of Purdue Opioids.

- 65. Although Plaintiff believes and therefore avers that reliance is not a necessary element of the UTPCPL violations set forth herein, Plaintiff and the Class, at all relevant times, justifiably relied to their detriment on Defendants' serial failures to comply with its legal obligations, flagrant misrepresentations and deceptions regarding both the illusory benefits and the very real risks of utilizing Purdue Opioids and chronic opioid therapy, and thus suffered an ascertainable loss as a result of the Defendants' failure to comply with such obligations.
- 66. In addition, Plaintiff further believes and therefore alleges that justifiable detrimental reliance is presumed as a result of the materiality of the transactions at issue.
- 67. By reason of the foregoing, Plaintiff and the Class have been harmed and damaged, entitling them, pursuant to 73 P.S. § 201-9.2, to injunctive relief, actual damages, statutory damages, treble damages and costs and reasonable attorneys' fees.

WHEREFORE, Plaintiff and the Class respectfully request that this Honorable Court enter judgment against Defendants on Count I and award Plaintiff and the Class actual and statutory damages for each instance of unfair or deceptive acts including, but not limited to, each instance in which Defendants misrepresented and/or deceptively represented the efficacy and risks associated with, or otherwise obfuscated the truth regarding the therapeutic uses of Purdue Opioids and chronic opioid therapy, treble damages, together with interest, costs of litigation, reasonable attorneys' fees, in amounts to be determined by the Court and such other relief as the Court deems appropriate.

COUNT II

UNJUST ENRICHMENT/RECISSION/RESTITUTION

- 68. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.
- 69. Defendants are the manufacturer, marketer, seller, and/or supplier of Purdue Opioids. Through the wrongful and deceptive conduct described at length above, Defendants have reaped substantial profits from the sale of Purdue Opioids. Yet, Defendants' profits would have been significantly and substantially reduced but for its wrongful, deceptive and unlawful conduct.
- Accordingly and as described in this Class Action Complaint, Defendants have been unjustly enriched by its unlawful, deceptive and wrongful conduct. Defendants should not be permitted to retain the proceeds from the benefits conferred upon them by Plaintiff and the Class (i.e., the purchase and/or reimbursement for purchase of Purdue Opioids). Defendants knew that Plaintiff and the Class paid for, or reimbursed for purchases of, Purdue Opioids that were not medically necessary, generally ineffective, and fundamentally unsafe. Moreover, the use of Purdue Opioids in the treatment of chronic pain and/or other long-term medical conditions offered no greater benefits than those offered by less expensive medications and treatment options.
- 71. It is unjust and inequitable to permit Defendants to enrich themselves at the expense of Plaintiff and the Class by retaining the benefit of the various expenditures for PURDUE Opioid prescriptions that were not medically necessary, effective, or, alternatively, no more efficacious than less expensive, substantially safer medical alternatives, or that were simply the result of Defendants' own self-created demand due to its own deceptive

marketing strategies. Accordingly, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution and/or rescission to Plaintiff and the Class.

WHEREFORE, Plaintiff and the Class respectfully requests that this Honorable Court enter judgment in their favor and against Defendants for compensatory and actual damages related to their purchases and reimbursement for purchases of Purdue Opioids, in amounts to be determined by the Court, together with interest, costs of litigation, attorneys' fees, and any other such relief as this Honorable Court may deem just and proper.

COUNT III

BREACH OF IMPLIED WARRANTIES

- 72. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.
- 73. Defendants, in the manufacture, marketing, and sale of Purdue Opioids impliedly warranted to Plaintiff and the Class that Purdue Opioids were appropriate for its particular and understood ordinary purpose as presented by Defendants: namely, the treatment of chronic pain and/or other long-term medical conditions.
- 74. Defendants and their agents, employees, servants, paid speakers, KOLs and/or other representatives knew or should have known that the Purdue Opioids were ineffective (and inherently dangerous) treatment options in the management of chronic pain and other long-term medical conditions.
- 75. Plaintiff and the Class reasonably relied upon the skill and judgment of Defendants and their agents, employees, servants, paid speakers, KOLs and/or other

representatives as to whether Purdue Opioids were of merchantable quality, safe, and fit for their intended uses as described by Defendants.

- 76. Pursuant to the Pennsylvania Commercial Code,⁴⁶ there exists an implied warranty of merchantability for Defendants' marketing and sale of Purdue Opioids. *See*, *e.g.*, 13 Pa.C.S. §§ 2314-15.
- 77. Defendants breached this implied warranty of merchantability by promoting, marketing, and selling Purdue Opioids as being fit for the "ordinary purpose" ascribed by Defendants (*i.e.*, the treatment of chronic pain and/or other long-term medical conditions) when, in fact, Purdue Opioids are inappropriate, dangerous, and unfit for that purpose.

WHEREFORE, Plaintiff and the Class respectfully requests that this Honorable Court enter judgment for them and against Defendants, for compensatory and consequential damages related to their purchases and reimbursements for purchases of Purdue Opioids, in amounts to be determined by the Court, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

COUNT IV

CIVIL CONSPIRACY

- 78. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.
- 79. Defendants conspired with various KOLs and Front Groups, and each other, as described throughout this Class Action Complaint in order to commit unlawful acts, including the serial violations of the UTPCPL detailed at length above. In particular, Defendants and the various KOLs and Front Groups knowingly and voluntarily agreed to

^{46 13} Pa.C.S. §§ 1101, et seq.

engage in unfair, misleading, and deceptive practices in order to promote the use of Purdue Opioids for the treatment of chronic pain and other long-term medical conditions. To that end, Defendants enlisted various KOLs and Front Groups to produce and disseminate statements and materials in furtherance of this common strategy, despite knowledge of the misleading nature of these activities.

- 80. Together with and in collusion with Front Groups including the APF, AGS, FSMB, APS, and AAPM, PURDUE agreed to deceptively and misleadingly promote the benefits and superiority of chronic opioid therapy and Purdue Opioids, while minimizing the associated risks. As part of these agreements, Defendants provided material, financial, and other forms of support to the Front Groups, which in turn used that support to more broadly disseminate the deceptive and misleading messaging regarding PURDUE Opioiods and chronic opioid therapy. The publications, marketing materials, and substantive representations produced and publicized by these Front Groups are each products of a civil conspiracy, and each instance of collaboration between Defendants and the Front Groups is evidence of an overt act taken in furtherance of that conspiracy.
- 81. Each of the participants in this conspiracy were fully aware of the deceptive and misleading nature of the statements, research, and other materials that they utilized in promoting Purdue Opioids. Nonetheless, Defendants and the Front Groups agreed to mislead and deceive Plaintiff and the Class regarding the risks, benefits, and alleged superiority of chronic opioid therapy and the Purdue Opioids, in exchange for increased pharmaceutical sales, financial contributions, reputational enhancements, and other pecuniary and professional benefits.

- 82. As outlined at length above, Defendants played an active role in determining the substance and format of the misleading and deceptive messaging issued by KOLs and Front Groups, including directly providing content, editing, and otherwise approving content produced by their co-conspirators. Defendants, KOLs, and the Front Groups also collectively ensured that these materials were widely disseminated by cooperative distribution, material support and republication. The result was an unrelenting stream of misleading information regarding the risks, benefits, and alleged superiority of chronic opioid therapy and the Purdue Opioids.
- 83. Even if Defendants did not directly disseminate or control the content of all of these misleading and deceptive representations, they are liable for conspiring with the third parties that did so (i.e., KOLs and Front Groups).
- 84. Defendants' conspiracy, and the consummation of that conspiracy via the overt acts described above, with these third parties were unlawful acts under Sections 201-2(4)(v), (vii), (viii), (xiv), and (xxi) of the UTPCPL.
- 85. As a result of Defendants' conspiracy and related unlawful acts, Plaintiff and the Class have been damaged and continue to be damaged by paying for the costs of or reimbursements for Purdue Opioids for the treatment of chronic pain and/or other long-term medical conditions.
- 86. Because Defendants' conspiracy ultimately caused doctors and other health care providers to prescribe (and, consequently, Plaintiff and the Class to pay for) long-term treatments via Purdue Opioids, Defendants caused and is responsible for those costs and claims.

WHEREFORE, Plaintiff and the Class respectfully requests that this Honorable

Court enter judgment for them and against Defendants, for direct and consequential damages related to their purchases and reimbursements for purchases of Purdue Opioids, in amounts to be determined by the Court, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

COUNT V

VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, ET SEQ.

- 87. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.
- 88. This claim is brought by the PFTHW against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, et seq.
- 89. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."
- 90. PFTHW is a "person," as that term is defined in 18 U.S.C. § 1961(3), and has standing to sue as it was and is injured in its business and/or property as a result of the Defendants' wrongful conduct described herein.
- 91. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . " 18 U.S.C. § 1962(c).
- 92. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. See 18 U.S.C. § 1962(d).

93. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

A. Description of the Defendants' Enterprise.

- 94. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).
- 95. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.
- 96. Defendants formed such an association-in-fact enterprise—referred to herein as "the Enterprise."
- 97. The Enterprise consists of Defendant PURDUE, including its employees and agents; Defendant ABBOTT, including its employees and agents; certain Front Groups described above, including but not limited to (a) the American Pain Foundation, including its employees and agents; (b) the American Academy of Pain Medicine, including its employees and agents; and (c) the American Pain Society, including its employees and agents; and certain KOLs, including but not limited to: (a) Dr. Russell Portenoy, and (b) Kathleen Foley.
- 98. Alternatively, each of the above-named Defendants and Front Groups constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the members of the enterprise conducted a pattern of racketeering activity. The separate legal status of each member of the Enterprise facilitated the fraudulent scheme and provided a hoped-for shield from liability for Defendants and their co-conspirators.

- 99. Alternatively, each of the Defendants, together with the Front Groups and the KOLs, constitute three separate, associated-in-fact Enterprises within the meaning of 18 U.S.C. § 1961(4).
- 100. The Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to sell drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons that obtain prescriptions for them.
- 101. To accomplish this purpose, the Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for the Defendants' opioid medications and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain (the "Scheme").

B. The Enterprise sought to fraudulently increase Defendants' profits and revenues.

- 102. At all relevant times, each Defendant was aware of the conduct of the Enterprise, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales and prescriptions of their opioid medications while the Front Groups and KOLs received direct payments from the Defendants in exchange their role in the Enterprise, and to advance the Enterprise's fraudulent marketing scheme.
- 103. The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but

not limited to: (1) the marketing, promotion, and advertisement of Defendants' opioid medicines; (2) the advocacy at the state and federal level for change in the law governing the use and prescription of Defendants' opioid medicines; (3) the issuance of prescriptions and prescription guidelines for Defendants' opioid medication; and (4) the issuance of fees, bills, and statements demanding payment for prescriptions of Defendants' opioid medications.

104. The persons engaged in the Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by the Defendants. Each of the Defendants funded and directed the operations of the KOLs and the Front Groups; in fact, the board of directors of each of the Front Groups are and were full of doctors who were on the Defendants' payrolls, either as consultants or speakers at medical events. Moreover, each of the Defendants coordinated and, at times, co-funded their activities in furtherance of the goals of the Enterprise. This coordination can also be inferred through the consistent misrepresentations described below. There is regular communication between each Defendant, each of the Front Groups, and each KOL in which information regarding Defendants' opioid medication and the Defendants' marketing and education scheme to increase prescription rates for those medications is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which the Defendants, the Front Groups, and the KOL share information regarding the operation of the Enterprise.

105. The Enterprise functioned as a continuing unit for the purposes of executing the Scheme and when issues arose during the Scheme, each member of the Enterprise agreed to take actions to hide the Scheme and the existence of the Enterprise.

- 106. Each Defendant participated in the operation and management of the Enterprise by directing its affairs as described herein.
- 107. While Defendants participated in, and are members of, the Enterprise, they have an existence separate from the Enterprise, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.
- exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives or detailers to promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers and provide a veneer of legitimacy to the Defendants' Scheme; (6) retaining KOLs to promote the use of their opioid medicines; and (7) concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.
- 109. In addition to the above described actions taken in furtherance of the Enterprise, Defendant PURDUE specifically orchestrated the affairs of the Enterprise by:
 (1) making a number of misleading statements described below; (2) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (3) participating in the Pain Care Forum, a coalition of drug makers, trade

groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid- related measures; (4) retaining KOLs, including Dr. Russell Portenoy and Kathleen Foley to tout the benefits of opioid medicines; (5) concealing the true nature of its relationship with the other members of the Scheme, and the Enterprise, including the Front Groups and the KOLs; and (6) partnering with Defendant ABBOTT to market and sell Purdue Opioids.

110. In addition to the above described actions taken in furtherance of the Enterprise, Defendant ABBOTT specifically orchestrated the affairs of the Enterprise by: (1) making a number of misleading statements described below; (2) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (3) participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid- related measures; (4) retaining KOLs, including Dr. Russell Portenoy and Kathleen Foley to tout the benefits of opioid medicines; (5) concealing the true nature of its relationship with the other members of the Scheme, and the Enterprise, including the Front Groups and the KOLs; and (6) partnering with Defendant PURDUE to market and sell Purdue Opioids.

111. The Front Groups orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent advocacy groups, when in fact their operating budgets are entirely comprised of contributions from opioid drug manufacturers; (3) lobbying against federal and state proposals to limit opioid use; (4) publishing treatment guidelines that advised the

prescription of opioids; (5) engaging in 'unbranded' advertisement for opioid medicines; (6) hosting medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks; and (7) concealing the true nature of their relationship with the other members of the Enterprise.

- 112. In addition to the above described actions taken in furtherance of the Enterprise, the American Pain Foundation specifically orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making a number of public statements, detailed herein, advocating for the prescription of opioids; (2) holding itself out to be an independent and scientific body despite maintaining an operating budget comprised almost entirely of donations from Defendants, including Defendants; (3) consistently lobbying against federal and state proposals to limit opioid use; (4) publishing treatment guidelines which encouraged the prescription of opioid medicines including the 2009 "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review"; and (5) sponsoring medical education programs advocating for the prescription of opioid medicines.
- 113. In addition to the above described actions taken in furtherance of the Enterprise, the American Academy of Pain Medicine specifically orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making a number of public statements, detailed herein, advocating for the prescription of opioids; (2) holding itself out to be an independent and scientific body despite maintaining an operating budget comprised almost entirely of donations from Defendants; (3) consistently lobbying against federal and state proposals to limit opioid use; (4) publishing treatment guidelines

which encouraged the prescription of opioid medicines; and (5) sponsoring medical education programs advocating for the prescription of opioid medicines.

- 114. In addition to the above described actions taken in furtherance of the Enterprise, the American Pain Society specifically orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making a number of public statements, detailed herein, advocating for the prescription of opioid medications; (2) holding itself out to be an independent and scientific body despite maintaining an operating budget comprised almost entirely of donations from Defendants; and (3) publishing treatment guidelines which encouraged the prescription of opioid medicines including the 2009 "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review."
- 115. The KOLs orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent, when in fact there are systematically linked to and funded by opioid drug manufacturers; and (3) concealing the true nature of their relationship with the other members of the Enterprise.
- 116. Without the willing participation of each member of the Enterprise, the Scheme and the Enterprise's common course of conduct would not have been successful.
- 117. The members of the Enterprise directed and controlled the ongoing organization necessary to implement the Scheme at meetings and through communications of which Plaintiff cannot fully know at present, because such information lies in the Defendants' and others' hands.

C. Predicate acts: mail and wire fraud.

- 118. To carry out, or attempt to carry out, the scheme to defraud, the members of the Enterprise, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).
- 119. Specifically, the members of the Enterprise have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.
- 120. The multiple acts of racketeering activity which the members of the Enterprise committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."
- 121. The racketeering activity was made possible by the Enterprise's regular use of the facilities, services, distribution channels, and employees of the Enterprise.
- 122. The members of the Enterprise participated in the Scheme by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.
- 123. The members of the Enterprise used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their Scheme through common misrepresentations, concealments, and material omissions.
- 124. In devising and executing the illegal Scheme, the members of the Enterprise devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and

the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

- 125. For the purpose of executing the illegal Scheme, the members of the Enterprise committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal Scheme.
- 126. The Enterprise's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:
 - a. Mail Fraud: The members of the Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically Purdue Opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.
 - b. Wire Fraud: The members of the Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically Purdue Opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.
- 127. Defendants Defendants false or misleading use of the mails and wires include, but are not limited to: (1) a May 31, 1996 press release announcing the release of OxyContin and indicating that the fear of its addictive properties is exaggerated; (2) a 1990 promotional video in which Dr. Portenoy, a paid PURDUE KOL, understated the risk of opioid addiction; (3) a 1998 promotion video which erroneously cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (4) statements made on its 2000 "Partners Against Pain" website which claimed that the addiction risk of OxyContin was very low; (5) literature distributed to physicians which erroneously cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (6) August 2001 statements to

Congress by PURDUE Executive Vice President and Chief Operating Officer Michael Friedman regarding the value of OxyContin in treating chronic pain; (7) a patient brochure entitled "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain" indicating that OxyContin is non-addicting; (8) a 2001 statement by Senior Medical Director for PURDUE, Dr. David Haddox, indicating that the 'legitimate' use of OxyContin would not result in addiction; (9) multiple communications by PURDUE'S sales representatives regarding the low risk of addiction associated with opioids; (10) statements included in promotional materials for opioids distributed to doctors via the mail and wires; (11) statements in a 2003 Patient Information Guide distributed by PURDUE indicating that addiction to opioid analgesics in properly managed patients with pain has been reported to be rare; (12) telephonic and electronic communications to doctors and patients indicating that signs of addiction in the case of opioid use are likely only the signs of under-treated pain; (13) statements in PURDUE'S Risk Evaluation and Mitigation Strategy for OxyContin indicating that drug-seeking behavior on the part of opioid patients may, in fact, be painrelief seeking behavior; (14) statements made on PURDUE'S website and in a 2010 "Dear Healthcare Professional" letter indicating that opioid dependence can be addressed by dosing methods such as tapering; (15) statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin indicating that long-term opioid use improves patients' function and quality of life; (18) statements made in advertising and a 2007 book indicating that pain relief from opioids improve patients' function and quality of life; (19) telephonic and electronic communications by its sales representatives indicating that opioids

will improve patients' function; and (20) electronic and telephonic communications concealing its relationship with the other members of the Enterprise.

- 128. The American Academic of Pain Medicine made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made in a 2009 patient education video entitled "Finding Relief: Pain Management for Older Adults" indicating the opioids are rarely addictive; and (2) telephonic and electronic communications concealing its relationship with the other members of the Enterprise.
- 129. The American Pain Society Quality of Care Committee made a number of false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) a May 31, 1996 press release in which the organization claimed there is very little risk of addiction from the proper use of drugs for pain relief; and (2) telephonic and electronic communications concealing its relationship with the other members of the Enterprise.
- 130. The American Pain Foundation ("APF") made a number of false and misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made by an APF Executive Director to Congress indicating that opioids only rarely lead to addiction; (2) statements made in a 2002 amicus curiae brief filed with an Ohio appeals court claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment of chronic pain; (3) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain" indicating that the risks of addiction associated with opioid prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that opioid users are not 'actual addicts;' (5) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain"

indicating that even physical dependence on opioids does not constitute addiction; (6) claims on its website that there is no ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that opioids can improve daily function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Enterprise.

- 131. The KOLs, including Russell Portenoy and Kathleen Foley, made a number of misleading statements in the mail and wires in violation of 18 U.S.C. § 1341 and § 1343, described above, including statements made by Dr. Portenoy in a promotional video indicating that the likelihood of addiction to opioid medications is extremely low. Indeed, Dr. Portenoy has since admitted that his statements about the safety and efficacy of opioids were false.
- 132. The mail and wire transmissions described herein were made in furtherance of Defendants' Scheme and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them; increase the prescription rate for opioid medications; and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain.
- 133. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of the Scheme.

- 134. The members of the Enterprise have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. 1962(d), the members of the Enterprise conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants and the members of the Enterprise in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or minimize losses for the Defendants and their named and unnamed co-conspirators throughout the illegal scheme and common course of conduct.
- 135. The members of the Enterprise aided and abetted others in the violations of the above laws.
- 136. To achieve their common goals, the members of the Enterprise hid from Plaintiff and the public: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with Defendants' opioid medications; and (3) the true nature of the relationship between the members of the Enterprise.
- 137. Defendants and each member of the Enterprise, with knowledge and intent, agreed to the overall objectives of the Scheme and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their co-conspirators had to agree to conceal their fraudulent scheme.
- 138. The members of the Enterprise knew, and intended that, Plaintiff and the public would rely on the material misrepresentations and omissions made by them and suffer damages and a result.

- 139. As described herein, the members of the Enterprise engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiff and the public based on their misrepresentations and omissions.
- 140. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.
- 141. The true purposes of Defendants' Scheme were necessarily revealed to each member of the Enterprise. Nevertheless, the members of the Enterprise continued to disseminate misrepresentations regarding the nature of Defendants' opioid medications and the functioning of the Scheme.
- 142. Defendants' fraudulent concealment was material to Plaintiff and the public. Had the members of the Enterprise disclosed the true nature of the Defendants' opioid medications, the PFTHW would not have acted as it did, including relying on Defendants' misrepresentations to its detriment.
- 143. The pattern of racketeering activity described above is currently ongoing and open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

D. PFTHW has been damaged by Defendants' RICO violations.

144. By reason of, and as a result of the conduct of the Enterprise and, in particular, its pattern of racketeering activity, the PFTHW and the public have been injured in their business and/or property in multiple ways, including but not limited to increased

health care costs, increased human services costs, costs related to dealing with opioid-related crimes and emergencies, and other public safety costs, as fully described above.

145. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to the PFTHW, who are entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).

WHEREFORE, Plaintiff and the Class respectfully requests that this Honorable Court enter judgment for them and against Defendants, for direct and consequential damages related to their purchases and reimbursements for purchases of Purdue Opioids, in amounts to be determined by the Court, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

ANAPOL WEISS

SOL H. WEISS, ESQUIRE

DAVID S. SENOFF, ESQUIRE

Hillary B. Weinstein, Esquire

CLAYTON P. FLAHERTY, ESQUIRE

130 N. 18^{TH} STREET, SUITE 1600

PHILADELPHIA, PA 19103

JAY EDELSON*

RAFEY S. BALABANIAN*

BENJAMIN H. RICHMAN*

EDELSON PC

350 North LaSalle, 13th Floor

CHICAGO, ILLINOIS 60654

*Pro Hac Vice Admission to be sought

DATED: OCTOBER 23, 2017